



## **U.S. PATENT DOCUMENTS**

| Exam.<br>Initials |          | Document<br>Number | Date      | Name              | Class | Sub-  | Filing Date  |
|-------------------|----------|--------------------|-----------|-------------------|-------|-------|--------------|
| шишаіз            |          | Nulliber           |           | l .               |       | class | (if          |
|                   | <b>.</b> | 4.701.000          | 10/10/100 |                   |       |       | appropriate) |
| FM                | AA       | 4,791,099          | 12/13/88  | Aroonsakul        | 514   | 171   |              |
| FM                | AB       | 4,897,389          | 1/30/90   | Aroonsakul        | 514   | 171   |              |
| FM                | AC       | 4,898,856          | 2/6/90    | Aroonsakul        | 514   | 171   |              |
| FΜ                | AD       | 4,898,857          | 2/6/90    | Aroonsakul        | 514   | 171   |              |
| FM                | AE       | 4,902,680          | 2/20/90   | Aroonsakul        | 514   | 171   |              |
| FM.               | AF       | 5,017,470          | 5/21/91   | Aroonsakul        | 435   | 4     |              |
| FM                | AG       | 5,391,381          | 2/21/95   | Wong, et al.      | 424   | 473   |              |
| FM                | AH       | 5,855,920          | 1/5/99    | Chein             | 424   | 568   |              |
| FM                | AI       | 5,397,771          | 3/14/95   | Bechgaard, et al. | 514   | 2     |              |
| FM                | AJ       | 5,434,146          | 7/18/95   | Labrie, et al.    | 514   | 169   |              |
| FM                | AK       | 5,550,107          | 8/27/96   | Labrie            | 514   | ll.   |              |
| FM                | AL       | 5,691,169          | 11/25/97  | Dalbage, et al.   | 438   | 69.7  |              |
| FM                | AM       | 5,424,199          | 6/13/95   | Goeddel, et al.   | 435   | 69.4  |              |
| FM                | AN       | 5,563,131          | 10/8/96   | Berliner, et al.  | 514   | 177   |              |
| FM                | AO       | 5,391,381          | 2/21/95   | Wong, et al.      | 424   | 473   |              |
| FM                | AP       | 4,727,041          | 2/23/98   | Aroonsakul        | 436   | 8     |              |
| FM                | AQ       | 5,691,325          | 11/25/97  | Sandyk            | 424   | 601   |              |

## FOREIGN PATENT DOCUMENTS

| Exam.<br>Initials |    | Document<br>Number | Date | Country | Class | Sub-<br>class | Trans<br>Yes | slation<br>No |
|-------------------|----|--------------------|------|---------|-------|---------------|--------------|---------------|
|                   | AQ |                    |      |         |       |               |              |               |

OTHER ART (Including Title, Author, Date, Pertinent Pages, etc.)

|                   |    | OTHER ART (Including Title, Author, Date, Pertinent Pages, etc.)   |
|-------------------|----|--|
| Exam.<br>Initials |    | Document Identification  |
| FM                | AR | "Administration of Human Somatotropin in Levodopa-Treated Patients With Parkinsonism" by Paul S. Papavasiliou et al., Arch Neurol, Vol. 36, October 1979.  |
| FM                | AS | "Long-Term Influence of Levodopa on Bone Mass and Growth Hormone in Postmenopausal Women with Parkinson's Disease" by H. Rico, et al., Clinical Neuropharmacology, Vol. 10, No. 1, p87-91, 1987. |
| FIY               | AT | "Clinical Studies of the Cholinergic Deficit in Alzheimer's Disease" by Bonnie M. Davis, MD, et al., Journal of the American Geriatrics Society, Vol. 33, No. 11.                                |
| FM                | AU | "Disturbances of Pituitary Function in Central Nervous System Disease" by Glenn T. Peake, MD, et al., Medical Clinics of North America, Vol. 52, No. 2, March 1968.                              |

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| Form PTO-1449 (Modified)                  | Attr. Docket No. 000 15.P002    | Serial No. 09/ <del>385,133</del> <b>762.015</b> |
| List of Patents & Publications Statemenan | Edmund Y. M. Chei               | n  |
| (Use several sheets if necessary)         | Filing Date:<br>August 25, 1999 | Examiner: Muezie, F.<br>Art Unit 1654            |

|     | <b>-</b> | AV | "Growth Hormone Response in Parking & Di  |
|-----|----------|----|---|
| L.  | FM       |    | "Growth Hormone Response in Parkinson's Disease" by J.D. Parkes, et al., The Lancet, February 28, 1976.   |
| F   | -M       | AV | "Blood Levels of FSH, LH, TSH, And GH in Parkinsonian patients Before and During L-Dopa Treatment" by P.O. Lundberg, <i>Acta Neurol</i> .  Scandinav., Vol. 48, p427-432, 1972  |
| F   | FM       | AX | Hormone and Somatostatin" by George C. Cotzias, et al., <i>The Basal Ganglia</i> , 1976.  |
|     | FM       | AY | Contraceptive Preparations on Experimental Allergic Encephalomyelitis" by Barry G. Arnason et al., Boston MA  |
| F   | M        | AZ | "Molecular Biology of Neurological and Psychiatric Disorders. I. Effect of Parkinsonism, Age, Sex and L-Dopa on Platelet Monoamine Oxidase" by E.A. Zeller, et al., Journal of Neutral Transmission, 30, p63, 77, 1076  |
| F   | M        | BA | Path. Jap., 29(3), p457-469 1979  |
| F   | M        | BB | Neurologischer Sicht" by Sigrid Poser, Fortschr. Neurol. Psychiat., 45, 1977.   |
| FI  |          | BC | "Contraccezione Orale e Sclerosi Multipla" by A. Ghezzi, et al., Archivio per le Scienze Mediche, 136, 1979.  |
| FI  |          | BD | "Estrogens and Extrapyramidal System" by P. Bedard, et al., <i>The Lancet</i> , December 24 & 31, 1977.   |
| FI  | 4        | BE | "Étude des Androgenes Plasmatiques Chez les Femmes Atteintes de Maladies Auto-Immunes" by M. Dougados, et al., Revue du Rhumatisme, 1984, 51(3), p145-149.  |
| FN  |          | BF | "Observations in a Preliminary Open Trial of Estradiol Therapy for Senile Dementia-Alzheimer's Type" by Howard Fillit, et al.,  Psychoneuroendocrinology, Vol. 11, No. 3, p337-345, 1986.  "Metabolic Effects of GH: A Particular of CH: A Particular |
| FM  | 1        | BG | Deficient Adults After Cessation of Linear Growth" by A. Juul, et al., Department of Growth and Reproduction, University of Copenhagen, Denmark. Horm Res (Switzerland) 1995, 44 Suppl 3, p64-72, ISSN 0301-0163, Journal Code GBI.   |
| FA  |          |    | "Insulin-Like Growth Factor I Alters Peripheral Thyroid Hormone Metabolism in Humans: Comparison with Growth Hormone" by M.A. Hussain, et al., Division of Endocrinology and Metabolism, University Hospital of Zurich, Switzerland. Eur J Endocrinol (Norway) May 1996, 134(5) p563-7, ISSN 0804-4643, Journal Code BXU.   |
| Fiy |          |    | "Improved Final Height in Girls with Turner's Syndrome Treated with Growth Hormone and Oxandrolone" by K.O. Nilsson, et al., Department of Pediatrics, University Hospital Malmo, Sweden. <i>J Clin Endocrinol Metab</i> (United States) Feb 1996, 81(2) p635-40, ISSN 0021-972X, Journal Code HRB.   |
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| Form PTO-1449 (Modified)                 | Atty Docket No. 000115.P002         | Serial No.<br>09/3 <del>85,133</del> 782,015 |
| List of Patents & Publications Statement | Applicant(s):<br>Edmund Y. M. Chein |  |
| (Use several sheets if necessary)        | Filing Date:<br>August 25, 1999     | Examiner: Muezie, F. Art Unit 1654           |

| FM | ВЈ      | "Insulin, Insulin-Like Growth Factor-Binding Protein-1, and Sex Hormone-Binding Globulin in Patients with Turner's Syndrome: Course Over Age in Untreated Patients and Effect of Therapy with Growth Hormone Alone and in Combination with Oxandrolene" by G. Haeusler, et al., Pediatric Department, University of Vienna, Austria. <i>J Clin Endocrinol Metab</i> (United States) Feb 1996, 81(2) p536-41, ISSN 0021-972X, Journal Code HRB. |
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| FM | BK      | "Growth Hormone Deficiency in Adults: Characteristics and Response to Growth Hormone Replacement" by S.A. Lieberman, et al., Department of Internal Medicine, University of Texas Medical Branch, Galveston, 77555-1060, USA. <i>J Pediatr</i> (United States) May 1996, 128 (5 Pt 2) pS58-60, ISSN 0022-3476, Journal Code JLZ.   |
| FM | BL      | "Effect of Anabolic Hormones and Insulin-Like Growth Factor-I on Muscle Mass and Strength in Elderly Persons" by W.J. Carter, et al., Memorial Veterans Hospital, Little Rock, Arkansas, USA. <i>Clin Geriatr Med</i> (United States) Nov 1996, 11(4) p735-48, ISSN 0749-0690, Journal Code CLN.   |
| FM | BM      | "Screening for PIT1 Abnormality by PCR Direct Sequencing Method by Y. Irie, et al., Department of Laboratory Medicine, Osaka University Medical School, Japan. <i>Thyroid</i> (United States) Jun 1995, 5(3) p207-11, ISSN 1050-7256, Journal Code BJW.  |
| FM | BN      | "Trophic Factor Supplementation: Effect on the Age-Associated Changes in Body Composition" by R.S. Schwartz, et al., Division of Gerontology and Geriatric Medicine, Harborview Medical Center, Seattle, USA. <i>J Gerontol A Biol Sci Med Sci</i> (United States) Nov 1995, 50 Spec No p151-6, ISSN 1079-5006, Journal Code CBA.  |
| FM | ВО      | "Treatment of Growth Hormone-Deficient Adults with Recombinant Human Growth Hormones Increases the Concentration of Growth Hormone in the Cerebrospinal Fluid and Affects Neurotransmitters" by J.O. Johansson, et al., Department of Internal Medicine, University of Goteborg, Sweden.  Neuroendocrinology (Switzerland) Jan 1995, 61(1) p57-66, ISSN 0028-3835, Journal Code NY8.   |
| FM | BP      | "Adult Growth Hormone Deficiency" by J.O. Jorgensen, et al., Medical Department M (Endocrinology and Diabetes), Aarhus Kommunehospital, Denmark. <i>Horm Res</i> (Switzerland) 1994, 42(4-5) p235-41, ISSN 0301-0163, Journal Code GBI.  |
| FM | BQ      | "Effects of Recombinant Human Growth Hormone on Metabolic Indices, Bodycomposition, and Bone Turnover in Health Elderly Women" by L. Holloway, et al., Aging Study Unit, Palo Alto Veterans Affairs Medical Center, California 94304. <i>J Clin Endocrinol Metab</i> (United States) Aug 1994, 79(2) p470-9, ISSN 0021-972X, Journal Code HRB.   |
| FM | BR<br>· | "Treatment of Growth Delay in Boys With Isolated Growth Hormone Deficiency" by A. Albanese, et al., Medical Unit, Institute of Child Health, London, UK. Eur J Endocrinol (Norway) Jan 1994, 130(1) p65-9, ISSN 0804-4643, Journal Code BXU.   |

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|          |          | BS    | "Management of the Short Stature Due to Pubertal Delay in Boys" by L.   |
|----------|----------|-------|---|
| F        | H        |       | Adan, et al., Pediatric Endocrinology Unit, Hopital et Faculte Necker-  |
| 1 ′      | "        |       | Enfants Malades, Paris, France. J Clin Endocrinol Metab (United States)   |
|          |          |       | 11 00 1774, 70(4) 04/0-82, ISSN U071-977X [ournal Code LIDD   |
| -        |          | BT    | Aging and Growth Hormone" by K.K. Ho. et al. Garger Institute 6   |
| <i> </i> | M        |       | I Would Research, St. Vincent's Hospital Sydney Australia II. n   |
|          |          |       | 1 \0 "\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\  |
|          | ] .      | BU    | 1 I Caulicill Of Additis with Growth Hormone (CLI) Deficiences in   |
| -        | ا ر .    |       | 1 Recombined In Tullian City by R. A. Rengtsson et al. Donostrosest C   |
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| 1        |          |       | 1 5 woden. J Clin Endocrinol Metab (United States) Feb 1003 76(2) -200  |
| <b>-</b> |          | BV    | 1 17, 1001 VV21-3/2A. JOURNAL CORE HRR  |
| 1        | 1        | DΥ    | "Regulation of Growth Hormone Binding Protein in Man: Comparison of   |
| F        | M        |       | I Ou Cincinglogiably and imminonreginitation Mathoda" her to to   |
| 1 ''     | 7        |       | I win Out vali mismule of Medical Research St Vincent's Hospital Column 1   |
| 1        |          |       | Australia. J Clin Endocrinol Metab (United States) Feb 1993, 76(2) p302-8, ISSN 0021-972X, Journal Code HRB.                                |
|          | Ī        | BW    | "Growth Hormone Therapy in Turner's Syndrome. Impact of Injection   |
| <b> </b> |          |       | Frequency and Initial Bone Age" by C. Rongen-Westerlaken, et al.,   |
| 1 F/     | M        |       | Department of Pediatrics, University of Utrecht The Netherlands Am I  |
|          |          |       | 1013 Child (United States) Jul 1992, 146(7) p817-20, ISSN 0002 0222   |
|          | -        |       | Journal Code 303.   |
|          |          | 3X    | "Nocturnal Thyrotropin Surge in Growth Hormone-Deficient Children" by   |
| FA       | ,        | 1     | O. Mullecill, Et al., Developmental Endocrinology Rranch Mational   |
| ′ ′      | 7        | į     | misutule of Cilia Realth and Hilman Development, National Institute of  |
|          |          |       | Health, Bethesda, Maryland 20892. J Pediatr (United States) Aug 1992,   |
|          | +B       | Y     | 121(2) p214-20, ISSN 0022-3476, Journal Code JLZ.  "Effects of Human Growth Hamman in M. Code JLZ.  |
| FM       |          | _     | "Effects of Human Growth Hormone in Men Over 60 Years Old" by Daniel Rudman, MD, et al., The New England Journal of Medicine, July 5, 1990, |
|          |          | ı     | Vol. 323, No. 1.  |
| iFΗ      | , B      | z     | "Restoring Ebbing Hormones May Slow Aging" by Jane E. Brody, The  |
|          |          | 1     | 110W 101K 11/1(ES, JUIV 18, 1997  |
| FH       |          | Α     | "Life Extension Interview", Life Extension, November 1996, p.21, 27   |
| FM       | ,  C     | _ [   | Diave Montel. How I III Gonna Beat MS" by John Rlosser Mational   |
| , , ,    |          | i     | Enquirer, September 7, 1999   |
| <b>J</b> | $\int C$ |       | "Multiple Sclerosis: The Immune System's Terrible Mistake" by Oeter   |
| FIN      | 7        |       | Taskina, MiD, FilD, The Harvara Mahaney Neuroscience Institute I  |
|          | C        |       | 011 116 Drum, Pall 1990, VOI. 3. NO. 4  |
| FIM      |          | ۱.    | "Evaluation of Progression in Multiple Sclerosis by Magnetic Resonance  |
| 1 / /    |          |       | Imaging (MRI)", National Institute of Neurological Disorders and Stroke (NINDS).  |
| FM       | CI       | E T   | "Growth Factors and Myelin Paganagation in No. 111  |
| 1 61     |          | _   , | "Growth Factors and Myelin Regeneration in Multiple Sclerosis" by HD Webster, <i>Mult Scler</i> , Apr 1997; 3(2); p113-20.                  |
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|   | Form PTO-1449 (Modified)                 | Atty Docket No. 000115.P002        | Serial No.<br>09/385,133 782,015      |
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|   | (Use several sheets if necessary)        |                                    | Examiner: Muezie, F.<br>Art Unit 1654 |

|        | CF  | "Insulin-Like Growth Factor I Treatment Reduces Clinical Deficits and      |
|--------|-----|--|
| FM     |     | Lesion Severity in Acute Demyelinating Experimental Autoimmune             |
| 1 / 7/ |     | Encephalomyelitis" by X. Liu, et al., Mult Scler, Apr 1995, 1(1), p2-9.    |
|        | CG  |  |
|        | CG  | 1 0 r  |
| FM     |     | Insulin-Like Growth Factor-I Treatment on Clinical Deficits, Lesion        |
| 1 17   |     | Severity, Glial Responses, and Blood Brain Barrier Defects" by W. Li, et   |
|        |     | al., J Neuropathol Exp Neurol, May 1998, 57(5), p426-38.                   |
|        | CH  |  |
| FM     |     | in Acute Non-Demyelinative Experimental Autoimmune Encephalomyelitis"      |
|        |     | by X. Liu, <i>J Neurosci Res</i> , Mar 1997, 47(5), p531-8.                |
|        | CI  | "Insulin-Like Growth Factor-I Given Subcutaneously Reduces Clinical        |
| FM     |     | Deficits, Decreases Lesion Severity and Up-Regulates Synthesis of Myelin   |
| 1779   | 1   | Proteins in Experimental Autoimmune Encephalomyelitis" by DL Yao, Life     |
|        |     | <i>Sci</i> , 1996, 58(16), p1301-6.  |
|        | Cl_ | "Insulin-Like Growth Factor-I Treatment Reduces Demyelination and Up-      |
| FM     |     | Regulates Gene Expression of Myelin-Related Proteins in Experimental       |
| 1 1 1  |     | Autoimmune Encephalomyelitis" by DL Yao, Proc Natl Acad Sci USA,           |
|        |     | June 20, 1995, 92(13), p6190-4.  |
|        | CK  | "A 48-Week (24-Week Baseline Followed by a 24-Week Treatment) Phase        |
| ,      |     | II Pilot Study of the Tolerability and Effect/Efficacy of Subcutaneously   |
| FM     |     | Administered Insulin-Like Growth Factor-I (rhIGF) (CEP-151) in Multiple    |
| 1      |     | Sclerosis (MS) Patients", National Institute of Neurological Disorders and |
|        |     | Stroke (NINDS).  |
|        | CL  | "Retrospective Analysis of the Effects of Low Dose, High Frequency         |
| FM     |     | Human Growth Hormone on Serum Lipids and Prostate Antigen" by              |
| ' ' '  |     | Edmund Y. Chein, MD, JD, et al.  |
| FH     | CM  | Palm Springs Life Extension Institute Manual, December 26, 1995.           |

Examiner: F. Moezie T. Moezie Date Considered: 2/18/0

**Examiner:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.